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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/661,094

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Kirsty Jane Dodgson

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EXAMINER

HINES, JANA A

ART UNIT

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MAIL DATE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/661,094	Applicant(s) DODGSON, KIRSTY JANE	
	Examiner JaNa Hines	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 and 44-57 is/are pending in the application.
- 4a) Of the above claim(s) 2-7, 10-14, 20-22, 24 and 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 8, 9, 15-19, 23, 25 and 44-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>5/7/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment Entry

1. The amendment filed May 5, 2008 has been entered. Claims 1 and 50-53 have been amended. Claims 2-7, 10-14, 20-22, 24 and 26-31 have been withdrawn from consideration. Claims 32-43 are cancelled. Claims 56-57 have been newly added. Claims 1, 8-9, 15-19, 23, 25 and 44-57 are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claims 50-53 under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendments and arguments.

Response to Arguments

3. Applicant's arguments filed May 5, 2008 have been fully considered but they are not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. The written description rejection of claims 1, 8-9, 15-19, 23, 25 and 44-55 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record.

The rejection is maintained for reasons already of record. The rejection is on the grounds that the specification teaches the structure of only a single representative

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species of SEQ ID NO:2, 3 and 4 and the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality of hybridizing to SEQ ID NO:2, 3 or 4. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention. With respect to claims 1, 8, 9 and 46-49, there is no description of polypeptides having at least 80%, 85%, 90%, 95% or 97% sequence identity to SEQ ID NO:2, 3 or 4. Also there is no support for the primers or probe consisting of 15 to 40 nucleotides which include SEQ DI NO:2, 3 or 4.

Applicants assert that hybrid formation and percent of nucleic acid sequence identity convey a common structure. While it is agreed that with aid, one of skill in the art could identify all the nucleic acid sequence with at least 80% sequence identity to SEQ ID O:2, 3 or 4. However, there is no teaching regarding which 20% of the nucleotides can vary from SEQ ID NO:2, 3 or 4 and still results in oligonucleotides that form effective hybrids to thereby detect or determine the presence or amount of hybrid formation to be indicative of detect *vanA* in a sample. Furthermore, there is no disclosed or art-recognized correlation between any structure other than SEQ ID NO:2, 3 or 4. Like wise, the specification does not place any structure, chemical functional limitations on the polynucleotide probe per se. The recitation of primers hybridizing does not convey a common structure or function. No information, beyond the characterization of a probes having SEQ ID NO:3 and primers having SEQ ID NO:2 and 4 have been

provided, which would indicate that applicants were not in possession of the claimed genus of any probes and primers that consist of 15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4.

Since the disclosure fails to describe the common attributes or structural characteristics that identify the members of the genus, and because the genus of nucleic acid molecules of is highly variable, the function of hybridization alone is insufficient to describe the genus of nucleic acid molecules. The specification teaches SEQ ID NO:2, 3 and 4. There is no description of oligonucleotides consisting of 15 to 40 nucleotides with at least 80% sequence identity to SEQ ID NO:2, 3 or 4. SEQ ID NO:2 has 18 amino acids, SEQ ID NO:3 has 27 amino acids and SEQ ID NO:4 has 20 amino acids. There is no description of probes and primers consisting of 15 to 40 nucleotides, when SEQ ID NO:2, 3 and 4 do not have 40 nucleotides. There is no description of what the additional nucleotides are. There is no description of a probe or primer that has at least 80% sequence identity to a sequence with additional unknown nucleotides. The specification fails to describe any other representative species by any identifying characteristics or properties. Therefore the full breadth of the claims fails to meet the written description provision of 35 USC 112, first paragraph and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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5. The new matter rejection of claims 1, 8-9, 15-19, 23, 25 and 44-57 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The rejection is on the grounds that neither the specification nor originally presented claims provides support for a method to detect *vanA* in a sample, comprising: a) contacting a sample suspected of comprising amplified *vanA* nucleic acid with at least one *vanA*-specific oligonucleotide probe under conditions effective to form a hybrid between the *vanA*-specific oligonucleotide probe and *vanA* nucleic acid in the sample, wherein the *vanA*-specific oligonucleotide probe consist of 15 to 40 nucleotides and has a sequence with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3, wherein the amplified *vanA* nucleic acid is obtained with a first and second oligonucleotide primer each consisting of 15 to 40 nucleotides, wherein the first oligonucleotide primer has a sequence with at least 80% nucleic acid sequence identity to SEQ ID NO:2, and the second oligonucleotide primer has a sequence with at least 80% nucleic acid sequence identity to SEQ ID NO:4, wherein the sequence of the probe is one which is effective to form a hybrid with SEQ ID NO:3 or its complement, wherein the sequence of the first primer is one which is effective to form a hybrid with the complement of SEQ ID NO:2, and wherein the sequence of the second primer is one which is effective to form a hybrid with the complement of SEQ ID NO:4; and b) detecting or determining the presence or amount of hybrid formation between the probe and nucleic acid in the sample, wherein hybrid formation is indicative of *vanA* nucleic acid in the sample.

Applicants assert that page 13 discloses probes having 80% sequence identity. However Page 13 states that Probes substantially correspond to a nucleic acid sequence if the percentage of identical bases or the percentage of perfectly complementary bases between the probe and its target sequence is from 100% to 80%. The comparison in the specification is different than the comparison of the instant claims. The specification provides support for comparing the probes and the target, while the claim compares the probe to SEQ ID NO:3, and not the target. Therefore, applicants support does not overcome the new matter rejection.

Applicants urge that the specification at page 6 discloses oligonucleotides corresponding to nucleotides 851-868 of SEQ ID NO:2, nucleotides 870-896 of SEQ ID NO:3 and 898 to 917 of SEQ ID NO:4 for support of probes and primers consisting of 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:2, 3 or 4 or the complement of SEQ ID NO:2, 3 or 4 that hybridizes to SEQ ID NO:2, 3 or 4. However, there is no teaching of a first oligonucleotide primer that has at least 80% nucleic acid sequence identity to SEQ ID NO:2, 3 or 4. However there is no teaching of the *vanA* specific oligonucleotide probe that consist of 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3 that hybridizes to SEQ ID NO:3; a first oligonucleotide primer that has at least 80% nucleic acid sequence identity to SEQ ID NO:2, wherein the first primer hybridizes to the complement of SEQ ID NO:2, and a second oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:4 and wherein the second primer hybridizes to the complement of SEQ ID NO:4. Therefore, despite applicants'

assertions to the contrary, it appears that the entire specification appears to fail to recite support for the *vanA* specific oligonucleotide probe and oligonucleotide primers. Thus, applicants' arguments are not persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. The rejection of claims 1, 8-9, 15-19, 23,25 and 44-57 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained for reasons of record.

a) Claims 1 is unclear. The amendment to claim 1 does not overcome the rejection. The rejection is on the grounds that a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions

of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949).

In the present instance, the claims are still drawn to a *vanA-specific* oligonucleotide probe that consist of 15 to 40 nucleotides with at least 80% nucleic acid sequence identity to SEQ ID NO:3 or the complement of SEQ ID NO:3; two oligonucleotide primers each consisting of 15 to 40 nucleotides, wherein a first oligonucleotide primer has at least 80% nucleic acid sequence identity to SEQ ID NO:2; and a second oligonucleotide primer has at least 80% nucleic acid sequence identity SEQ ID NO:4.

SEQ ID NO:2 has 18 amino acids, SEQ ID NO:3 has 27 amino acids and SEQ ID NO:4 has 20 amino acids. The "consisting of" language does not clarify the claim. Claim 1 recites the broad limitation of probes or primers consisting of 15 to 40 nucleotides, yet the narrower statement of the range/limitation is drawn to SEQ ID NO:2, 3 and 4 which do not have 40 nucleotides; the sequences have 18, 27 and 20 nucleotides respectively. The claims and specification fail to disclose what the other nucleotides are. Thus the metes and bounds of the claim cannot be ascertained by one of ordinary skill in the art and clarification is required to overcome the rejection.

b) The phrase "effective to form a hybrid" in the claim is a relative phrase which renders the claim indefinite. It is suggested that claim 1 recite the precise hybridization conditions in order to overcome the rejection. For instance, the specification at pages 21-22 teaches specific conditions such as having a PCR reaction mixtures containing

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50mM KCl, 10mM Tris-HCl pH 8.3, 2.5 mM MgCl₂, 0.4/zm of each of the two primers, 200 uM of each of the four dNTPs and 1.25 Units of Taq DNA polymerase (Perkin Elmer). PCR reactions are then subjected to thermal cycling (3 minutes at 95°C followed by 30 cycles of 1 second at 95°C and 1 second at 55°C) using a Perkin Elmer 480™ thermal cycle and subsequently analyzed by standard ethidium bromide-stained agarose gel electrophoresis. As such, the action of hybridizing is dependant upon specific conditions that are not recited in the claims and specification fails to define the metes and bounds of the phrase. Therefore one skilled in the art would not be readily apprised as to the metes and bounds of the hybridizing probes or primers. While it is noted that new claim 56 recites limitations on the sequence of the probes and primers, this limitation does not overcome the need for the appropriate hybridization language in the claims. Therefore, the rejection is maintained.

Conclusion

7. No claims allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/JaNa Hines/

Examiner, Art Unit 1645

/Mark Navarro/

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